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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/741,664	12/21/2000	Ayoub Rashtchian	0942.3910003/RWE/BJD	7736

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EXAMINER
ARTHUR, LISA BENNETT

ART UNIT	PAPER NUMBER
1634	6

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/741,664	Applicant(s) RASHTCHIAN ET AL.	
	Examiner Lisa B. Arthur	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. The specification is objected to because page 1, line 1 does not reference parent application 09/049,021 from which this application is a continutation.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-3, 30-31 and 44-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claim 1 is indefinite over the recitation of "stable composition" because this term makes the claims unclear with regard to what "stable" is relative. "Stable" does not confer a clear meaning to the composition because the claims do not recite for what the composition is to be used.

Similarly, this claim is indefinite over the recitation of "working concentration" because the meaning of this term is unclear without a recitation describing the kind of "work" the composition is to be used for. The concentration of reagents would be different depending upon the type of "work" to be performed.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

5. Claims 1-2, 30 and 44-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Sealice et al. Sealice et al. teaches a stable composition containing working concentrations of Taq DNA polymerase, a Tris-MgCl buffer, dATP dTTP, dGTP, dCTP and an antibody which specifically binds to Taq polymerase (column 17, example 2, lines 37-47). The concentrations of the Taq polymerase, buffer, deoxynucleoside triphosphates and antibody are at "working concentrations" because the composition was successfully used, i.e. worked, in a PCR amplification reaction. Sealice et al. Teach that the anti-DNA polymerase antibodies provided the advantage of reducing or eliminating the formation of non-specific products in PCR methods (see abstract).

6. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Heath et al. (Nucleic Acids Research (1993) 21(24): 5782-5785).

Heath et al teach a stable composition for nucleic acid amplification comprising a mixture of Taq DNA polymerase (a thermostable DNA polymerase), a salt buffer of Tris, KCl and MgCl and deoxynucleotides (page 5782, col. 2, para. 2). The concentration of Taq DNA polymerase is 0.05U/ul which is 50U/milliliter (claim 8). Heath et al teach that the concentration of deoxynucleotides is 200 uM (claim 28). Heath et al contacted this composition with a template nucleic acid in order to amplify the nucleic acid (claim 33 and 40). Heath et al. Inherently teach the limitation recited in claims 24-25 that the polymerase retains 90% activity for at least 4 weeks

when stored at 20 to 25C and for at least a year when stored at 4C because the composition of the claims and the composition of Heath et al. are the same and therefore both compositions have the same characteristics.

7. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Lundberg. Lundberg et al. teach a stable composition for nucleic acid amplification comprising either a Taq DNA polymerase or a Pfu DNA polymerase at 25U/milliliter, a salt buffer and deoxynucleotides (page 4, col. 1-2). Lundberg et al teach that the concentration of deoxynucleotides is 200 uM (claim 28).Lundberg et al contacted this composition with a template nucleic acid in order to amplify the nucleic acid (claim 33 and 40). Lundberg et al inherently teach the limitation recited in claims 24-25 that the polymerase retains 90% activity for at least 4 weeks when stored at 20 to 25C and for at least a year when stored at 4C because the composition of the claims and the composition of Lundberg et al. are the same and therefore both compositions have the same characteristics.

8. Claims 1,2 are rejected under 35 U.S.C. 102(b) as being anticipated by Barnes et al. (PNAS (1994) 91:2216-2220). Barnes et al teach a stable composition for nucleic acid amplification comprising a mutant form of Taq, Klentaq1, which is exonuclease free and Pfu DNA polymerase, a salt buffer and 250uM dNTPs (page 2217, col. 1, para 2). Barnes et al. Also teach compositions containing VENT and DEEP VENT DNA polymerases in combination with a Taq polymerase page 2218, col. 2).

9. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Gelfand et al. (US Pat 5,420,029). Gelfand et al. Disclose a stable composition for nucleic acid amplification comprising 25U/milliliter of Tma DNA polymerase, a salt buffer and 200uM dNTPs.

10. Claims 1-3,30,31 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 9008839 Eastman Kodak Co. The 9008839 PCT discloses a premixed multi component reagent for sequencing comprising a thermostable DNA polymerase such as Taq polymerase at a concentration of 100-500 U/ml., buffer, deoxynucleotides and dideoxynucleotides. The composition also contains Mg salt and a non-ionic surfactant. The PCT also discloses a kit for sequencing containing this composition.

11. Claims 1-3 are rejected under 35 U.S.C. 102(a) as being anticipated by Slatko (MOLECULAR BIOTECHNOLOGY (1996) 6:311-322).

Slatko et al teaches a method for nucleic acid thermal cycle dideoxy sequencing which uses a composition containing a thermostable polymerase such as Taq, Vent, Taq derivatives, Deep Vent exo-, Pfu exo-, in a salt buffer containing MgCl, a non-ionic surfactant (triton X-100) deoxynucleotides and dideoxynucleotides (page 311). Slatko et al. teach an example of using 2U of Vent exo- DNA polymerase (page 313).

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 31,45 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eastman Kodak PCT 9008839 in view of Sealice et al. The rejection is directed to the embodiment of the claims drawn to composition and a kit for sequencing containing the polymerase, buffer, dNTPs and ddNTPs and the anti-DNA polymerase antibody.

The 9008839 PCT discloses a premixed multi component reagent for sequencing comprising a thermostable DNA polymerase such as Taq polymerase at a concentration of 100-500 U/ml., buffer, deoxynucleotides and dideoxynucleotides. The composition also contains Mg salt and a non-ionic surfactant. The PCT also discloses a kit for sequencing containing this composition.

The Eastman Kodak PCT does not teach a composition of kit for sequencing additionally contain an anti-DNA polymerase antibody.

However, Sealice et al. teaches a stable composition and a kit containing working concentrations of Taq DNA polymerase, a Tris-MgCl buffer, dATP dTTP, dGTP, dCTP and an antibody which specifically binds to Taq polymerase (column 17, example 2, lines 37-47). The concentrations of the Taq polymerase, buffer, deoxynucleoside triphosphates and antibody are at "working concentrations" because the composition was successfully used, i.e. worked, in a PCR amplification reaction. Sealice et al. Teach that the anti-DNA polymerase antibodies provided the advantage of reducing or eliminating the formation of non-specific products in PCR methods (see abstract).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified the composition and kit of Eastman-Kodak to include the anti-DNA polymerase antibody of Sealice et al. In order to make the claimed invention as a whole. The ordinary artisan would have been motivated to have added the antibody of Sealice et al. To the composition and kit of Eastman-Kodak in order to have achieved the expected benefit taught by Sealice of reducing and eliminating the formation of non-specific annealing products in the PCR based sequencing reaction of Eastman-Kodak. Alternatively, the ordinary artisan would also have been motivated to have made a kit containing the reagents in the Eastman-Kodak kit and the reagents in the Sealice et al. Kit in order to achieve the expected benefit of making a kit for PCR amplification of a target and subsequent sequencing of the target

since these two steps are commonly applied to the characterization of the same target nucleic acid.

14. No claims are allowable over the prior art.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa Arthur whose telephone number is (703) 308-3988. The examiner can normally be reached on Monday-Wednesday from 7:00 AM to 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

LISA B. ARTHUR
PRIMARY EXAMINER
GROUP 1800

March 20, 2002